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M WAYNE WESTERN
THORPE, NORTH & WESTERN
P O BOX 1219
SANDY, UT 840911219

EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,686	PIAO ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

PD

DETAILED ACTION

Claims **1-23** are pending in this application.

Information Disclosure Statement

The information disclosure statement filed 1/29/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the IDS filed is improper. Firstly, the IDS filed must be a clean copy so that it may be signed and dated. Secondly, the references cited on a PTO-892 from another application must be submitted on A PTO-1449 form so that the examiner may sign and date it. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of EP 0092918.

Cha teaches an injectable biodegradable block copolymeric drug delivery liquid having

reverse thermal gelation properties comprising an aqueous solution having uniformly contained therein between about 3 and 40% by weight of (a) an effective amount of a drug intimately contained in (b) a biodegradable block copolymer composition. The copolymer has a reverse gelation temperature and is made of a hydrophobic A polymer block such as poly (alpha-hydroxy acids) or poly (ethylene carbonates) and hydrophilic B polymer block of polyethylene glycol. See abstract. The block copolymer is a triblock copolymer, i.e. ABA or BAB. See column 7 in its entirety. Polymer block A makes up about 15-50% by weight of the copolymer and polymer B makes up about 50-85%. See column 12, lines 53-60. Instant poly (alpha-hydroxy acids) are taught on column 7, lines 39-55 with an average molecular weight between 500 to 10,000 Daltons. Block B has an average molecular weight between 1,000 to 20,000 Daltons.

Cha teaches the controlled release of actives that corresponds to the biodegradation of the polymeric matrix. Cha teaches the use of the polymer matrix to release an array of drugs such as hormones, anti-cancer agents, antibiotics, proteins, polypeptides, and antiinflammatories in the amount of 0.1-10%. See column 4, lines 40-46, column 9, lines 26-31, and column 10, lines 10-25. . Cha teaches the instant polypeptides and anticancer agent claimed in 5-8 and 13-17. See claims 14 and 16.

Cha teaches parenterally administering the liquid into the animal by intramuscular, intraperitoneal, subcutaneous or similar injection with the liquid forming a gel depot of the drug and biodegradable block polymer as the temperature of the liquid is raised by the body temperature of the animal the reverse gelation temperature of the block copolymer. The drug is released at a controlled rate from the copolymer, which biodegrades into non-toxic products.

Cha teaches the degradation rate can be adjusted by proper selection of the poly(.alpha.-hydroxy acid) utilized in forming the biodegradable hydrophilic A block, i.e. this reads on claim 22.

Lastly, Cha teaches the method of polymerizing the individual components (individual blocks) of the triblock and then forming the triblock in a reactor. See examples.

Cha et al do not teach a mixture of two triblock copolymers.

EP teaches a continuous release formula of polypeptides for injectable hydrogel implants. See page 2, lines 60-63. The implant is made any pharmaceutically acceptable copolymer wherein polymer A is a hydrophobic polymer and B is a hydrophilic polymer of the formula ABA or BAB. See page 3, lines 25-31. The mechanism of release involves the swelling of the polymer when the polypeptide and copolymer are immersed in water. When equilibrium state has been reached the degradation of the hydrophobic region begins. The partially degraded copolymer has a greater swellability so that continued hydrolysis leads to progressive water uptake and further increase in polypeptide desorption which compensates for its decreasing concentration; thus maintaining its continuous release. The appropriate design of the copolymer material, the initial swelling of the hydrogel, and desorption of the active can be controlled to extend the release of the active. Further, by blending *different* copolymers, each having its own properties such as molecular weight, molecular weight distribution, block structure, hydrophilicity, degradation properties, and diffusion properties, the release rate and the duration of release can be varied. See page 4, lines 29-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cha et al and EP and combine two triblock copolymers

with different physical and chemical properties. One would have been motivated to do so since EP teaches different copolymer blends allows for the variation of the release rate and duration of release of the active agent. Further since EP teaches a similar polymeric system, one of ordinary skill in the art would look at the guidance provided by EP and expect similar results.

With regard to claim 19, since Cha teaches the method of synthesizing different triblock copolymer types but lacks in the teachings of combining different types of copolymers in one system, the combination of Cha and EP would render the process of claim 19 obvious.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of Shah et al (6,451,346).

Cha teaches an injectable biodegradable block copolymeric drug delivery liquid having reverse thermal gelation properties comprising an aqueous solution having uniformly contained therein between about 3 and 40% by weight of (a) an effective amount of a drug intimately contained in (b) a biodegradable block copolymer composition. The copolymer has a reverse gelation temperature and is made of a hydrophobic A polymer block such as poly (alpha-hydroxy acids) or poly (ethylene carbonates) and hydrophilic B polymer block of polyethylene glycol. See abstract. The block copolymer is a triblock copolymer, i.e. ABA or BAB. See column 7 in its entirety. Polymer block A makes up about 15-50% by weight of the copolymer and polymer B makes up about 50-85%. See column 12, lines 53-60. Instant poly (alpha-hydroxy acids) are taught on column 7, lines 39-55 with an average molecular weight between 500 to 10,000 Daltons. Block B has an average molecular weight between 1,000 to 20,000 Daltons.

Cha teaches the controlled release of actives that corresponds to the biodegradation of the polymeric matrix. Cha teaches the use of the polymer matrix to release an array of drugs such as

hormones, anti-cancer agents, antibiotics, proteins, polypeptides, and antiinflammatories in the amount of 0.1-10%. See column 4, lines 40-46, column 9, lines 26-31, and column 10, lines 10-25. . Cha teaches the instant polypeptides anticancer agent claimed in 5-8 and 13-17. See claims 14 and 16.

Cha teaches parenterally administering the liquid into the animal by intramuscular, intraperitoneal, subcutaneous or similar injection with the liquid forming a gel depot of the drug and biodegradable block polymer as the temperature of the liquid is raised by the body temperature of the animal the reverse gelation temperature of the block copolymer. The drug is released at a controlled rate from the copolymer, which biodegrades into non-toxic products.

Cha teaches the degradation rate can be adjusted by proper selection of the poly(.alpha.-hydroxy acid) utilized in forming the biodegradable hydrophilic A block, i.e. this reads on claim 22.

Lastly, Cha teaches the method of polymerizing the individual components (individual blocks) of the triblock and then forming the triblock in a reactor. See examples.

Cha et al do not teach a mixture of two triblock copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See

column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cha et al and Shah et al and combine two triblock copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Further since Shah teaches a similar polymeric system as the instant the system except for the teaching of the instant molecular weights of each triblock copolymer; therefore one of ordinary skill in the art would look at the guidance provided by Shah and expect similar results.

With regard to claim 19, since Cha teaches the method of synthesizing different triblock copolymer types but lacks in the teachings of combining different types of copolymers in one system, the combination of Cha and Shah would render the process of claim 19 obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321I may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/186462.

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 8, and independent claim 28 are directed to a composition comprising one or more biodegradable copolymeric drug carriers comprising 1) AB or ABA or BAB block copolymers wherein A block is a polyester and B clock is a PEG and 2) a liquid PEG, PEG derivative or a mixture thereof. Dependent claims 7, 14, and 34 further comprises a drug. Lastly, copending claims 35-41 are directed to a method of preparing the biodegradable polymeric system of claim 1, 8, and 28 respectively.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter since the instant claims are directed to a combination of two triblock copolymers and a drug copending claims may contain one or more biodegradable triblock copolymers and a drug. Thus, the two applications are obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/167768.

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 8, independent claim 15, and independent claim 22, are directed to a composition comprising one or more biodegradable copolymeric drug carriers comprising 1) AB or ABA or BAB block copolymers wherein A block is a polyester and B clock is a PEG and 2) a liquid PEG, PEG derivative or a mixture thereof. Dependent claims 6, 13, and 20 further comprises a drug. Lastly, copending claims 29-36 are directed to a method of preparing the biodegradable polymeric system.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter since the instant claims are directed to a combination of two triblock copolymers and a drug and copending claims may contain one or more biodegradable triblock copolymers and a drug. Thus, the two applications are obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/734740 in view of Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a

Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 4, independent claim 8, and independent claim 12, are directed to a composition comprising a biodegradable ABA or BAB block copolymers wherein A block is a polyester and B clock is a PEG and an effective amount of drug. Claim 18 and 23 are directed to a method of administering the polymeric drug delivery system wherein the system is liquid and administering the composition to a warm-blooded animal.

The copending claims do not claim the mixture of two triblock copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-

block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,592,899 in view Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties

comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19are directed to a process of preparing the polymeric system of claim 1.

US '899 claim 22 is directed to a biodegradable aqueous drug solution and method of administering the drug solution comprising (a) an effective amount of a drug; (b) a biodegradable polyester oligomer and (c) a biodegradable AB-type, ABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising: I) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 2400 to 4999; and (d) an aqueous solution.

US patent does not claim the mixture of two tri-block copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 09/827100 (which has been allowed) in view Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock

copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

09/827100 is directed to a drug delivery system (claim 1) and a method of preparing the system (claim 15) comprising a) a sparingly soluble particle, b) a protein or polypeptide, and c) a polymeric matrix. Claim 11 and 24 are directed to a biodegradable polymeric matrix. Claim 12 and 28 directed to a biocompatible matrix containing ABA block copolymers, BAB block copolymers, AB block copolymers or mixtures thereof.

Thus, the instant claims are directed to a combination of two tri-block copolymers and a drug and copending claims may contain a combination of triblock copolymers and a drug. Thus, the two applications are obvious modifications of each other since they are directed to similar subject matter.

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,201,072; 6,117,949; 6,004,573 in view Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000

Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19are directed to a process of preparing the polymeric system of claim 1.

US '573 is directed to a an aqueous biodegradable polymeric drug delivery composition possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug; and (b) a biodegradable ABA-type block copolymer of the formula: PLGA-PEG-PLGA where PLGA is a hydrophobic poly(lactide-co-glycolide) copolymer that comprises the A-blocks and PEG is a hydrophilic polyethylene glycol

polymer that comprises the B-block, said block copolymer having an average molecular weight of between about 3100 and 4500 wherein, in the block copolymer, the PLGA A-blocks comprise about 51 to 83% by weight of said copolymer and the PEG B-block comprises about 17 to 49% by weight of said copolymer. Further, US Patent claim 12 is directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

US'072 is directed an aqueous biodegradable polymeric drug delivery composition possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug and (b) a biodegradable ABA- or BAB-type tri-block polymer, said ABA triblock comprises: i) about 51 to 83% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and ii) about 17 to 49% by weight of a biodegradable, hydrophilic B polymer block comprising a polyethylene glycol(PEG), and wherein the tri-block copolymer having an average molecular weight of between about 2000 to 4990 and possessing reverse thermal gelation properties. Further, US Patent claim 26 is directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

US'949 is directed to an aqueous biodegradable polymeric drug delivery composition possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug; and (b) a biodegradable ABA- or BAB-type triblock polymer said ABA triblock having the formula: PL(G).sub.z-1 A-PEG-PL(G).sub.z-1 A

and said BAB triblock having the formula: PEG-PL(G).sub.z-1 A-PEG wherein z is an integer of 1 or 2, wherein the A block is represented by PL(G).sub.z-1 A such that when z is 2 the A block is a poly(lactide-co-glycolide) or PGLA copolymer, and when z is 1 the A block is a poly(lactide) or PLA polymer and wherein the B block is represented by PEG which is a hydrophilic polyethylene glycol polymer, said triblock polymer having a weight average molecular weight of between about 2000 to 4990, and wherein, in the triblock polymer, the PL(G).sub.z-1 A A-block comprises about 51 to 83% by weight of said polymer and the PEG B-block comprises about 17 to 49% by weight of said polymer. Further, US Patent claim 24 is directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

The above US patent do not claim the mixture of two tri-block copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties.

One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

Miscellaneous Remarks

The examiner notes that there are numerous applications and patents with the same assignee that may or may not contain double patenting issues; thus the examiner requests the identification of applications or patents that may contain similar subject matter.

Conclusion

None of the claims are allowed at time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

JOHN PAK
PRIMARY EXAMINER
GROUP 1600